REMARKS

These remarks are made in response to the Office Action dated December 12, 2007. The present invention provides a method for determining the binding affinity and/or stoichiometry of a binding complex between a binding factor and a probe, which uses fluorescence polarization and capillary electrophoresis to distinguish between a fluorescently-labeled probe and a complex containing both the probe and a factor which binds the probe where the method can be used to characterize the complex. The complex exhibits higher polarization than the probe because a small molecule, such as the probe, rotates freely in solution and tends to yield no polarization. Claims 2-4, 11-12, 16 and 24 are pending. Applicant requests reconsideration of the rejections of the pending claims. In this response Claim 24 has been amended to better describe what Applicant believes to be his invention.

I. REJECTION UNDER 35 U.S.C. § 112

Claim 24 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this response Applicant has amended claim 24 to remove the non-sequitur relating to "the laser-induced fluorescence polarization." This amendment is believed to overcome the rejection under 35 U.S.C. § 112, second paragraph, and Applicant respectfully asks that the rejection be withdrawn.

II. REJECTION UNDER 35 U.S.C. § 102

Claims 2, 11-12, 16 and 24, as amended, stand rejected under 35 U.S.C. § 102(a) as being anticipated by Wan et al. (Analytical Chemistry (2000)). Applicant traverses this rejection as it may be applied to the present claims.

The present applicant, Dr. Xiao-Chun Chris Le, is the senior author of the cited Wan et al. publication. With this response, Applicant submits a declaration which indicates that Dr. Wan was a post-doctoral trainee in Dr. Le's laboratory at the time the work reported in the cited publication was carried out. To the extent that the cited publication discloses aspects of the invention of the present application, those aspects were conceived solely by the present inventor, Dr. Le, and reduced to

practice in Dr. Le's laboratory in Alberta Canada, a NAFTA country. Dr. Wan's contributions to the cited publication were carried out under the direction and supervision of Dr. Le. Thus, the rejection of Claims 2, 11-12, 16 and 24 under 35 U.S.C. § 102(a) as being anticipated by Wan et al. (Analytical Chemistry (2000)) is improper. Applicant respectfully asks that the rejection of Claims 2, 11-12, 16 and 24 be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 103

Claims 2-4, 11-12, 16 and 24 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Laing et al. (U.S. Patent No. 6,331,392, hereafter "the '392 patent") in view of Le et al. (U.S. Patent No. 6,132,968, hereafter "the '968 patent"). Applicant traverses this rejection as it may apply to the present claims.

The Laing '392 patent is directed to identifying conformational changes in RNA. As was previously recognized, Laing et al. does not disclose the use of capillary electrophoresis as set forth in present claim 24. (*See* Office Action mailed January 30, 2006, at page 7.) The method of the Laing patent is asserted to detect the conformational change in a target RNA sequence when the hybridization of a fluorescently labeled probe is inhibited or modified through the interactions of a ligand with the target RNA sequence.

The method of the Le '968 patent is directed to detecting and/or quantitating at least one modification to a nucleic acid sequence of interest. Le cites the use of fluorescently labeled polypeptides as one exemplary method of identifying a modification to a nucleic acid sequence. Neither the Laing '392 patent, nor the Le '968 patent, suggest the method of the present application which provides a method for determining the binding affinity and/or stoichiometry between a binding factor and a probe by combining information obtained from electrokinetic chromatography and laser-induced fluorescence polarization.

The outstanding office action asserts that it would be within the ordinary skill in the art to correlate the results between two techniques of analysis for accurate determination or analysis of the complex to be studied, citing disclosures from the

Laing patent at col. 8, which states that "determination of the absolute amounts or ratios of stabilized and non-stabilized or folded and unfolded target RNA may be carried out using probes which comprise one or more fluorescent moieties." Determination of absolute amounts or ratios of stabilized and non-stabilized target RNAs differs significantly from the method of determining binding affinity and/or stoichiometry of a binding complex between a binding factor and a probe which can be achieved with the method of the present application. For example, one can determine the stoichiometry or binding ratio between a binding factor, such as a protein, and a probe. That is, one can determine whether one, two, or more copies of a particular binding factor interact with a particular probe by combining the results of the electrokinetic separation with the determination of the binding complex by laser-induced fluorescence polarization. This new, unrecognized result of combining the electrokinetic separation and the detection of the separated binding complexes by laser-induced fluorescence polarization does add new methods of obtaining information about binding complexes that was not provided by the nature and quality of the cited prior art. The cited disclosure of the Laing '392 patent does not suggest or provide motivation to use the method of the present invention to determine the binding affinity and/or stoichiometry of a binding complex between a binding factor and a probe as is claimed in present claim 24. Applicant submits that the present claims are patentably distinct from the disclosures of the cited references and respectfully requests that the rejection of the pending claims under 35 U.S.C. §103 be withdrawn.

IV. NON-STATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 2, 11, 16 and 24 stand rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6,132,968 ('968 Patent), the Le patent, in view of U.S. Patent No. 6,331,392 ('392 Patent), the Laing patent. Applicant believes that the rejection of the instant claims over the '968 patent, in view of the '392 patent, is made in error, and respectfully requests withdrawal of the rejection. As a first matter, the rejection as to the '392 patent is made in error as there is no common assignee or inventor between the present invention and the Laing '392 patent. *See* the MPEP at 800-16.

As a second matter, claims 1 and 9 of the '968 Le patent are directed to a method for quantitating at least one modification of interest in a deoxyribonucleic acid sequence contained in a sample, which is a different invention from the methods of the present application, which is directed to a method for determining the binding affinity and/or stoichiometry of a binding complex between a binding factor and a probe. Applicant respectfully requests that the rejection of claims 2, 11, 16 and 24 for non-statutory obviousness-type double patenting be withdrawn.

For the reasons set forth above, Applicant believes that claims 2-4, 11, 12, 16 and 24 are in condition for allowance and respectfully requests that each of the rejections set forth in the Office Action be withdrawn.

If the Examiner believes that prosecution of the present matter could be advanced by having a discussion with Applicant's representative, she is invited to contact the representative at (703) 838-6562.

Should any additional fees be required, the Commissioner is authorized to charge deficiencies or credit any overpayment to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY, L.L.P.

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By: Barbara W. Walker
Barbara W. Walker
Registration No. 35400

1737 King St Ste 500
Alexandria VA US 22314
703-836-6620